201-15416

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06/29/2004 10:36 AM

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Subject: Environmental Defense comments on Methoxymethanol (CAS# 4461-52-3)

(Submitted via Internet 6/29/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and pmsurana@celanese.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Methoxymethanol (CAS# 4461-52-3).

The test plan and robust summaries for methoxymethanol (MOM) were submitted by Celanese Limited. This substance is a transient equilibrium species that is present in mixtures of formaldehyde, methanol and water. This mixture apparently offers advantages for using formaldehyde as an intermediate in the production of urea-formaldehyde and melamine-formaldehyde resins, which are used for coatings, adhesives, molding compounds and other applications. According to the test plan, MOM has no known application in commerce other than as an incidental chemical in methanolic formaldehyde. The proportion of MOM in the mixture varies according to temperature, pH, water content and other factors. The test plan states that as the water content increases the amount of MOM decreases. The sponsor estimates, based on storage, transport and use conditions 150 million pounds of MOM are produced, shipped and used in the U.S. each year. The Celanese product (Methyl Formcel), apparently contains about 25% MOM, with the remaining 75% consisting of formaldehyde, methanol and several other equilibrium species.

The sponsor contends that existing data are adequate for all SIDS endpoints. This contention is based on the utilization of data from a series of Japanese studies conducted on an equilibrium mixture said to be similar, characterized as 46% MOM, 44% methanol and 10% water. Other equilibrium species were not identified in the Japanese mixture. The sponsor also contends that data from formaldehyde and methanol studies can be used as surrogates for MOM. Both of these contentions are, in part, true. However, additional data need to be provided before we can concur that no additional studies are needed. In particular, we ask for the following information:

1. A well-organized table of data needs to be provided that provides direct comparisons of the Celanese and Japanese mixtures. This table must show expected concentrations of all equilibrium species found in Methyl Formcel and the MOM mixture used in the Japanese studies. Also, existing toxicity data must be provided on those equilibrium species, as some of them may be found in concentrations of 5-10% and may influence patterns and/or potency of toxic reactions. If the Japanese and Celanese products are significantly different in composition, then we recommend that the sponsor conduct studies on all mammalian health endpoints using Methyl Formcel as the test substance. In support of this concern, we note that the sponsor argues that acute toxicity for Methyl Formcel cannot be predicted based on data from formaldehyde and methanol.

2. The sponsor needs to provide data on the metabolism of Methyl

Formcel and the Japanese mixture, as well as methanol and formaldehyde. Although, we agree that formaldehyde and methanol data are relevant, they do not address the real possibility that exposure to the mixture may alter metabolism and distribution characteristics of formaldehyde and/or methanol.

The aquatic toxicity data were obtained using Methyl Formcel as the test substance, so those data meet the requirements of the HPV program. We also note that the sponsor provides a convincing justification that the aquatic toxicities of MOM are primarily caused by formaldehyde.

The test plan, in several places, infers that rodent data are not relevant for evaluating human responses to formaldehyde and methanol. This information seems to be self-serving, as it does not also present the available evidence in support of the human relevance of the rodent studies. These statements should either be deleted or all of the available data presented and addressed in a more even-handed manner.

In the robust summaries of the combined repeat dose/reproductive/developmental study performed on the Japanese mixture, no information is provided on the histological methods used. This information is necessary for an evaluation of the adequacy of the study.

Thank you for this opportunity to comment.

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